Entering Trial Results Into ClinicalTrials.gov : An Experience with Small Drug Trials

NHGRI trials requiring results submission:

- Small trials (<50 participants),
- Trial data have NOT been in a database that is capable of generating reports (changing landscape),
- Principal investigators too busy to learn to do their own results submission.

Helpful hints:

- Have a staff member dedicated to learning how to navigate the Protocol Registration System (PRS).
- Data managers, fellows or graduate students/IRTAs are all possible. It particularly helps to be comfortable with databases, basic research analysis and statistics, and clinical terms.

Preparing to enter study results into the PRS

The Responsible Party (RP) should first check that the basic protocol information already in ClinicalTrials.gov is correct. In particular, pay attention to the description of the study design, the study arms, and the intervention(s). If these are not correct, edit and submit the corrections.

Get familiar with the format of study results in ClinicalTrials.gov

- Search ClinicalTrials.gov for studies that have a similar design and/or similar types of outcome measures to your own. You can search by disease terms, by Institute, etc. Look for studies that have results entered!
- When you find your example study, print the study results section. Study the tables shown and envision how your own data would fit in them. This will help you get your data into the correct format for entry.

Organize ALL information from Responsible Party BEFORE entering results

- Trial parameters:
  - Point of contact and IND/sponsor,
  - Recruitment dates,
  - Length of the study and its intervals,
  - Study arms (names and descriptions),
  - Numbers of subjects in each arm who enrolled, completed, and dropped out.

Organize ALL information from Responsible Party BEFORE entering results

- Baseline characteristics:
  - Numbers of males and females enrolled in each arm,
  - Categorical subject age information,
  - Mean subject age.
  - Any other characteristic useful in evaluating study results.

Baseline Measures

	Multi-Drug Regimen
Number of Participants [units: participants]	3
Age [units: participants]	
<=18 years	0
Between 18 and 65 years	3
>=65 years	0
Age [units: years] Mean ± Standard Deviation	51 ± 9
Gender [units: participants]	
Female	0
Male	3
Region of Enrollment [units: participants]	
United States	3

Information about the outcome measure(s)

- The primary outcome measure (required)
  - Which secondary measures will be entered?
- The measure(s) should be entered as a quantitative value - e.g., number of patients survived after a specified time interval, incidence of adverse events, a change in a laboratory measurement, etc.
- Determine the time frame of the outcome measure in specific terms (hours, days, weeks).
- May need some basic statistics (e.g., standard deviation or confidence interval).

Measure Type	Primary
Measure Title	Survival at 2 Years
Measure Description	The number of subjects surviving after 24 months on study.
Time Frame	24 months
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details suc
No text entered.

Reporting Groups

	Description
Multi-Drug Regimen	Losartan, 25 mg by mouth every night at bedtime; Zileuton, 1200 mg by mouth twice daily; N-acetylcysteine, 600 mg by mouth three times daily; Pravastatin, 20 mg by mouth e mouth three times daily. Erythromycin : Erythromycin tablet, 333 mg by mouth three times daily. Losartan : Losartan potassium tablet, 25 mg by mouth every night at bedtime. Zileuton : Zileuton tablet, 1200 mg by mouth twice daily. N-Acetylcysteine : N-acetylcysteine solution, 600 mg by mouth three times daily. Pravastatin : Pravastatin sodium tablet, 20 mg by mouth every night at bedtime.

Measured Values

	Multi-Drug Regimen
Number of Participants Analyzed [units: participants]	**2**
Survival at 2 Years [units: participants]	**0**

Information about adverse events in the study

- Separate the serious adverse events (SAEs) from other adverse events (AEs). There are standard definitions for what qualifies as an AE and a SAE.
- Minimum reporting requirement: All SAEs, and all AEs that occur at greater than 5% frequency in the study.

Information about adverse events in the study

- Classify the AEs by organ system. It is helpful to use a standard dictionary for your terms, such as MEDdra, available online from the NIH library.
- For each AE, obtain the number of participants affected (per arm), and number of events (per arm).

Think ahead

- Potential problem: what the RP is preparing for publication may not match what is to be entered in PRS.
  - You or the RP may have to re-analyze raw outcome data!
  - You or the RP may have to re-analyze adverse event information!
- Remember: print a similar study's results and envision your data in similar tables.

It’s a Process

- Practice a little. Enter some information, save, and view it. Nothing is final until you upload.
- The PRS staff is helpful. Ask questions. Be prepared to go through a couple iterations of editing depending on their feedback.
- The RP is ultimately responsible; he or she needs to check the results and certify them to upload results.
- Hopeful conclusion: once you’ve done one study, the process becomes much easier!